

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

BRISTOL-MYERS SQUIBB COMPANY)

Corporate Headquarters)
345 Park Avenue)
New York, NY 10154)

BRISTOL-MYERS SQUIBB PHARMA)
COMPANY)

Route 206 and Province Line Road)
Lawrenceville, NJ 08540,)

Plaintiffs,)

v.)

No. _____

DAVID KAPPOS, in his official capacity as)
Under Secretary of Commerce for Intellectual)
Property and Director of the United States)
Patent and Trademark Office)

Office of General Counsel)
United States Patent and Trademark Office)
P.O. Box 15667, Arlington, VA 22215)

Madison Building East, Room 10B20)
600 Dulany Street, Alexandria, VA 22314,)

Defendant.)

COMPLAINT

For their Complaint against David Kapos, Plaintiffs Bristol-Myers Squibb Company
("BMS") and Bristol-Myers Squibb Pharma Company ("BMS Pharma") hereby allege as
follows:

Nature of Action

1. This is an action by the assignees of five United States patents seeking review of the patent term adjustments granted by the Director of the United States Patent and Trademark Office (“PTO”) pursuant to 35 U.S.C. § 154(b).

2. All of the challenged PTO patent term adjustment determinations relied on an erroneous interpretation of 35 U.S.C. § 154(b) that this Court rejected in *Wyeth v. Dudas*, 580 F. Supp. 2d 138 (D.D.C. 2008), *appeal pending* No. 2009-1120 (Fed. Cir.).

Parties

3. Plaintiff BMS is a Delaware corporation with its principal place of business in New York.

4. Plaintiff BMS Pharma is a Delaware general partnership with its principal place of business in New Jersey.

5. Defendant David Kappos is sued in his official capacity as Under Secretary of Commerce for Intellectual Property and Director of the PTO. The Director of the PTO is designated by statute as the official responsible for determining the period of patent term adjustments, *see* 35 U.S.C. § 154(b)(3), and as the proper defendant in a suit seeking review of such determinations, *see id.* § 154(b)(4)(A).

Jurisdiction and Venue

6. This action arises under 35 U.S.C. § 154 and the Administrative Procedure Act, 5 U.S.C. §§ 701-706.

7. This Court has subject-matter jurisdiction over this action and is authorized to issue the relief sought pursuant to 28 U.S.C. §§ 1331, 1338(a), and 1361; 35 U.S.C. § 154(b)(4)(A); and 5 U.S.C. §§ 701-706.

8. Venue is proper in this Court under 35 U.S.C. § 154(b)(4)(A).

Background

9. Under 35 U.S.C. § 154(a)(2), a successful patent applicant is entitled to a 20-year patent term beginning on the date its application was first filed with the PTO. Because this period starts to run with the filing of the application rather than with the grant of the patent, any delay in the PTO's processing of an application reduces the applicant's effective patent term.

10. To prevent such administrative delays from causing unfair losses of patent protection, Congress directed the PTO to grant successful applicants upward adjustments of their patent terms to compensate for three categories of processing delay by the PTO. Those three categories, set forth in 35 U.S.C. § 154(b)(1)(A), (B), and (C), are known as "A delays," "B delays," and "C delays," respectively. Only "A delays" and "B delays" are at issue in this case.

11. "A delays" occur when the PTO fails to take one of several specified actions within a particular time period—for example, if the PTO does not "issue a patent within 4 months after the date on which the issue fee was paid ... and all other outstanding requirements were satisfied." 35 U.S.C. § 154(b)(1)(A)(iv). The statute provides that "the term of the patent shall be extended by 1 day for each day after the end of the period specified ... until the action described ... is taken." *Id.* § 154(b)(1)(A).

12. "B delays" occur when the PTO fails to issue a patent within 3 years of the filing of the patent application, excluding certain specified periods of delay. 35 U.S.C. § 154(b)(1)(B). As with "A delays," the statute provides for a day-for-day patent term adjustment to compensate for any "B delays": "[T]he term of the patent shall be extended by 1 day for each day after the end of that 3-year period until the patent is issued." *Id.*

13. In calculating a patent term adjustment, however, Congress directed that overlapping periods of “A delay” and “B delay” may not be double-counted: “To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.” 35 U.S.C. § 154(b)(2)(A). The dispute in this case concerns the proper interpretation of this provision.

14. The PTO has taken the position that whenever an application is subject to both an “A delay” and a “B delay,” those periods *always* “overlap” within the meaning of § 154(b)(2)(A)—even if they occur on different calendar days. *See* 69 Fed. Reg. 34,283 (June 21, 2004). The result of this interpretation is that an applicant is entitled to an adjustment equal to *either* the “A delay” or the “B delay,” whichever is longer, but never to an adjustment equal to the “A delay” *plus* the “B delay.”

15. This Court rejected the PTO’s interpretation of § 154(b)(2)(A) in *Wyeth v. Dudas*, 580 F. Supp. 2d 138 (D.D.C. 2008). Giving the words of the statute their plain meaning, the Court observed that “[t]he only way that periods of time can ‘overlap’ is if they occur on the same day.” *Id.* at 141. The Court thus held that “[i]f an ‘A delay’ occurs on one calendar day and a ‘B delay’ occurs on another, they do not overlap, and § 154(b)(2)(A) does not limit the extension to one day.” *Id.* at 141-142.

16. Notwithstanding the Court’s holding in *Wyeth*, the PTO has adhered to its erroneous interpretation of § 152(b)(2)(A). The agency thus continues to determine patent term adjustments in a manner that is contrary to the statute.

17. The PTO relied on this improper method in calculating the patent term adjustment applicable to each of the patents at issue in this case. If those adjustments had instead been

calculated in accordance with this Court's decision in *Wyeth*, Plaintiffs would have received the longer adjustments that they now seek in this suit.

18. This Complaint is timely filed under 35 U.S.C. § 154(b)(4)(A).

COUNT I

19. Plaintiffs incorporate paragraphs 1-18 as if fully set forth herein.

20. BMS is the assignee of United States Patent No. 7,589,193 ("the '193 patent").

21. The application for this patent was filed on September 23, 2005, and the patent issued on September 15, 2009.

22. The patent term adjustment determined by the Director and currently reflected on the patent is 433 days.

23. The Director's determination of the patent term adjustment was incorrect because it was based on the erroneous statutory interpretation that this Court rejected in *Wyeth v. Dudas*.

24. Under 35 U.S.C. § 154(b)(1)(A), the application for the patent was subject to an "A delay" of 433 days.

25. Under 35 U.S.C. § 154(b)(1)(B), the application was also subject to a "B delay" of 357 days.

26. None of the days of the "A delay" occurred on the same calendar day as any of the days of the "B delay."

27. Thus, under the correct interpretation of § 154(b)(2)(A) set forth by this Court in *Wyeth*, no days of the "A delay" overlap with the "B delay."

28. The total period of PTO delay in the processing of the patent application is therefore 790 days, which is equal to the "A delay" (433 days) plus the "B delay" (357 days).

29. Under 35 U.S.C. § 154(b)(2)(C), the applicable patent term adjustment “shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application.” The PTO determined that the period of applicant delay in the processing of the patent was 0 days.

30. Accordingly, the correct patent term adjustment under 35 U.S.C. § 154(b) should have been 790 days.

31. On October 27, 2009, BMS filed a timely Request for Reconsideration of Patent Term Adjustment under 35 U.S.C. § 154(b)(3)(B)(ii) and 37 C.F.R. § 1.705(d). The request demonstrated that in light of the *Wyeth* decision, the PTO’s calculation of the patent term adjustment was incorrect. Although the request indicated that the proper period of patent term adjustment was 789 days, BMS has now determined that the proper period of adjustment is 790 days. The Request for Reconsideration remains pending.

32. The PTO’s determination of the patent term extension for the ’193 patent was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law under 35 U.S.C. § 706(2)(A).

COUNT II

33. Plaintiffs incorporate paragraphs 1-18 as if fully set forth herein.

34. BMS is the assignee of United States Patent No. 7,589,088 (“the ’088 patent”).

35. The application for this patent was filed on December 21, 2005, and the patent issued on September 15, 2009.

36. The patent term adjustment determined by the Director and currently reflected on the patent is 589 days.

37. The Director's determination of the patent term adjustment was incorrect because it was based on the erroneous statutory interpretation that this Court rejected in *Wyeth v. Dudas*.

38. Under 35 U.S.C. § 154(b)(1)(A), the application for the patent was subject to an "A delay" of 589 days.

39. Under 35 U.S.C. § 154(b)(1)(B), the application was also subject to a "B delay" of 268 days.

40. None of the days of the "A delay" occurred on the same calendar day as any of the days of the "B delay."

41. Thus, under the correct interpretation of § 154(b)(2)(A) set forth by this Court in *Wyeth*, no days of the "A delay" overlap with the "B delay."

42. The total period of PTO delay in the processing of the patent application is therefore 857 days, which is equal to the "A delay" (589 days) plus the "B delay" (268 days).

43. Under 35 U.S.C. § 154(b)(2)(C), the applicable patent term adjustment "shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application." The PTO determined that the period of applicant delay in the processing of the patent was 0 days.

44. Accordingly, the correct patent term adjustment under 35 U.S.C. § 154(b) should have been 857 days.

45. On October 27, 2009, BMS filed a timely Request for Reconsideration of Patent Term Adjustment under 35 U.S.C. § 154(b)(3)(B)(ii) and 37 C.F.R. § 1.705(d). The request demonstrated that in light of the *Wyeth* decision, the PTO's calculation of the patent term adjustment was incorrect. Although the request indicated that the proper period of patent term

adjustment was 856 days, BMS has now determined that the proper period of adjustment is 857 days. The Request for Reconsideration remains pending.

46. The PTO's determination of the patent term extension for the '088 patent was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law under 5 U.S.C. § 706(2)(A).

COUNT III

47. Plaintiffs incorporate paragraphs 1-18 as if fully set forth herein.

48. BMS is the assignee of United States Patent No. 7,557,143 ("the '143 patent").

49. The application for this patent was filed on April 15, 2004, and the patent issued on July 7, 2009.

50. The patent term adjustment determined by the Director and currently reflected on the patent is 653 days.

51. The Director's determination of the patent term adjustment was incorrect because it was based on the erroneous statutory interpretation that this Court rejected in *Wyeth v. Dudas*.

52. Under 35 U.S.C. § 154(b)(1)(A), the application for the patent was subject to "A delays" of 682 days.

53. Under 35 U.S.C. § 154(b)(1)(B), the application was also subject to a "B delay" of 354 days.

54. Only 43 days of "A delays" occurred on the same calendar day as any of the days of the "B delay."

55. Thus, under the correct interpretation of § 154(b)(2)(A) set forth by this Court in *Wyeth*, only 43 days of the "A delays" overlap with the "B delay."

56. The total period of PTO delay in the processing of the patent application is therefore 993 days, which is equal to the “A delay” (682 days) plus the “B delay” (354 days) minus the period of overlap (43 days).

57. Under 35 U.S.C. § 154(b)(2)(C), the applicable patent term adjustment “shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application.” The PTO determined that the period of applicant delay in the processing of the patent was 29 days.

58. Accordingly, the correct patent term adjustment under 35 U.S.C. § 154(b) should have been 964 days, which is equal to the total period of PTO delay (993 days) minus the period of applicant delay (29 days).

59. On August 5, 2009, BMS filed a timely Request for Reconsideration of Patent Term Adjustment under 35 U.S.C. § 154(b)(3)(B)(ii) and 37 C.F.R. § 1.705(d). The request demonstrated that in light of the *Wyeth* decision, the PTO’s calculation of the patent term adjustment was incorrect. Although the request indicated that the proper period of patent term adjustment was 1007 days, BMS has now determined that the proper period of adjustment is 964 days. The PTO denied the request on November 19, 2009.

60. The PTO’s determination of the patent term extension for the ’143 patent—in both its initial determination and in its denial of the Request for Reconsideration—was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law under 5 U.S.C. § 706(2)(A).

COUNT IV

61. Plaintiffs incorporate paragraphs 1-18 as if fully set forth herein.

62. BMS Pharma is the assignee of United States Patent No. 7,514,430 (“the ‘430 patent”).

63. The application for this patent was filed on July 28, 2005, and the patent issued on April 7, 2009.

64. The patent term adjustment determined by the Director and currently reflected on the patent is 537 days.

65. The Director’s determination of the patent term adjustment was incorrect because it was based on the erroneous statutory interpretation that this Court rejected in *Wyeth v. Dudas*.

66. Under 35 U.S.C. § 154(b)(1)(A), the application for the patent was subject to an “A delay” of 537 days.

67. Under 35 U.S.C. § 154(b)(1)(B), the application was also subject to a “B delay” of 253 days.

68. None of the days of the “A delay” occurred on the same calendar day as any of the days of the “B delay.”

69. Thus, under the correct interpretation of § 154(b)(2)(A) set forth by this Court in *Wyeth*, no days of the “A delay” overlap with the “B delay.”

70. The total period of PTO delay in the processing of the patent application is therefore 790 days, which is equal to the “A delay” (537 days) plus the “B delay” (253 days).

71. Under 35 U.S.C. § 154(b)(2)(C), the applicable patent term adjustment “shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application.” The PTO determined that the period of applicant delay in the processing of the patent was 0 days.

72. Accordingly, the correct patent term adjustment under 35 U.S.C. § 154(b) should have been 790 days.

73. On June 1, 2009, BMS Pharma filed a timely Request for Reconsideration of Patent Term Adjustment under 35 U.S.C. § 154(b)(3)(B)(ii) and 37 C.F.R. § 1.705(d). The request demonstrated that in light of the *Wyeth* decision, the proper period of patent term adjustment was 790 days. The PTO denied the request on September 23, 2009.

74. The PTO's determination of the patent term extension for the '430 patent—in both its initial determination and in its denial of the Request for Reconsideration—was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law under 5 U.S.C. § 706(2)(A).

COUNT V

75. Plaintiffs incorporate paragraphs 1-18 as if fully set forth herein.

76. BMS is the assignee of United States Patent No. 7,491,725 ("the '725 patent").

77. The application for this patent was filed on July 29, 2005, and the patent issued on February 17, 2009.

78. The patent term adjustment determined by the Director and currently reflected on the patent is 214 days.

79. The Director's determination of the patent term adjustment was incorrect because it was based on the erroneous statutory interpretation that this Court rejected in *Wyeth v. Dudas*.

80. Under 35 U.S.C. § 154(b)(1)(A), the application for the patent was subject to "A delays" of 251 days.

81. Under 35 U.S.C. § 154(b)(1)(B), the application was also subject to a "B delay" of 203 days.

82. None of the days of the “A delay” occurred on the same calendar day as any of the days of the “B delay.”

83. Thus, under the correct interpretation of § 154(b)(2)(A) set forth by this Court in *Wyeth*, no days of the “A delay” overlap with the “B delay.”

84. The total period of PTO delay in the processing of the patent application is therefore 454 days, which is equal to the “A delay” (251 days) plus the “B delay” (203 days).

85. Under 35 U.S.C. § 154(b)(2)(C), the applicable patent term adjustment “shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application.” The PTO determined that the period of applicant delay in the processing of the patent was 37 days.

86. Accordingly, the correct patent term adjustment under 35 U.S.C. § 154(b) should have been 417 days, which is equal to the total period of PTO delay (454 days) minus the period of applicant delay (37 days).

87. On April 2, 2009, BMS filed a timely Request for Reconsideration of Patent Term Adjustment under 35 U.S.C. § 154(b)(3)(B)(ii) and 37 C.F.R. § 1.705(d). The request demonstrated that in light of the *Wyeth* decision, the PTO’s calculation of the patent term adjustment was incorrect. The request also identified the period of applicant delay, which the PTO had previously overlooked. The PTO granted the request in part on September 29, 2009, modifying the patent term adjustment to account for the period of applicant delay but rejecting BMS’s arguments based on the *Wyeth* decision.

88. On November 25, 2009, BMS filed a timely second Request for Reconsideration of Patent Term Adjustment under 35 U.S.C. § 154(b)(3)(B)(ii) and 37 C.F.R. § 1.705(d). The

request demonstrated that in light of the *Wyeth* decision, the proper period of patent term adjustment was 417 days. The second Request for Reconsideration remains pending.

89. The PTO's determination of the patent term extension for the '725 patent—in both its initial determination and in its denial of the first Request for Reconsideration—was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law under 5 U.S.C. § 706(2)(A).

Prayer for Relief

WHEREFORE, Plaintiffs pray that this Court:

1. Issue an Order changing the period of patent term adjustment for the '193 patent to 790 days and requiring Defendant to alter the term of the '193 patent to reflect the changed adjustment.

2. Issue an Order changing the period of patent term adjustment for the '088 patent to 857 days and requiring Defendant to alter the term of the '088 patent to reflect the changed adjustment.

3. Issue an Order changing the period of patent term adjustment for the '143 patent to 964 days and requiring Defendant to alter the term of the '143 patent to reflect the changed adjustment.

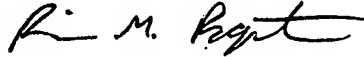
4. Issue an Order changing the period of patent term adjustment for the '430 patent to 790 days and requiring Defendant to alter the term of the '430 patent to reflect the changed adjustment.

5. Issue an Order changing the period of patent term adjustment for the '725 patent to 417 days and requiring Defendant to alter the term of the '725 patent to reflect the changed adjustment.

6. Grant such further and other relief as this Court deems just and proper.

Respectfully submitted,

Dated: December 23, 2009



Randolph D. Moss (D.C. Bar No. 417749)

Brian M. Boynton (D.C. Bar No. 483187)

WILMER CUTLER PICKERING

HALE AND DORR LLP

1875 Pennsylvania Avenue, N.W.

Washington, D.C. 20006

Telephone: (202) 663-6000

Facsimile: (202) 663-6363

E-mail: randolph.moss@wilmerhale.com

Attorneys for Plaintiffs

Bristol-Myers Squibb Company and

Bristol-Myers Squibb Pharma Company